Self-sufficiency in Vitamin A

@664. SHRI CHATURANAN MISHRA: Will the Minister of INDUSTRY be pleased to state:

(a) what is the estimated requirement of Vitamin A for control of blindness and other injections;

(b) whether Vitamin A is being manufactured in sufficient quantity or it is being imported, if so, details thereof; and

(c) whether self-sufficiency in the manufacture of Vitamin A is proposed to be achieved in the country to reduce its costs?

THE MINISTER OF INDUSTRY (SHRI J. VENGAL RAO): (a) The estimated requirement of Vitamin 'A' for control of blindness only is 100 million doses every year for 50 million eligible group of children (1—5 years).

(b) The production of Vitamin 'A' in the year 1986-87 (Actual) and 1987-88 (Target) has been of the order of 69.34 MMU and 160.00 MMU respectively. The deficit in production and demand is being met through imports.

(c) Yes, Sir.

Prices of Category I Drugs

665. DR. RATNAKAR PANDEY: Will the Minister INDUSTRY be pleased to refer to the answer to Unstarred Question 3521 given in the Rajya Sabha on the 28th March, 1988 and state:

(a) whether it is a fact that according to the Drugs Price Control Order, 1987 all single ingredient and combination formulations based on category I drugs will be treated as category I formulations;

(b) whether it is a fact that a number of combinations based on category I drugs are being sold at very high prices;

(c) whether it is a fact that neither his Ministry has fixed the prices of those combination formulations nor the companies have applied for reduction of prices;

(d) if so, the names of those combination formulations and reasons for the delay in reducing the prices as per reduction in MAPE; and

(e) what steps have been taken to give relief to the patients who are being overcharged since the announcement of DPCO, 1987?

THE MINISTRY OF INDUSTRY (SHRI J. VENGAL RAO): (a) Categorisation of formulations will be made as per provisions of DPCO, 1987 as further clarified in the guidelines issued by this Ministry on 9-12-1987. A copy of these guidelines is at the attached statement (*See* below).

(b) No instance of any category I formulations being sold at prices higher than those fixed by the Government has come to the notice of the Government.

(c) to (e) The Government has already reduced the prices of Category I formulations on the basis of leader prices fixed under DPCO, 1979. The prices of other formulations were fixed with 60 per cent mark-up. The Government has also directed all manufacturers of formulations which were hither-to in Category III of DPCO, 1979 and are now covered under Category I of DPCO, 1987 to submit applications in Form-2.

Statement

Guidelines for implementation of various provisions of DPCO, 1987

I. *Bulk Drugs*

The prices of all bulk drugs specified in the First and Second Schedules are controlled except Vitamins.

@Previously Unstarred Question 336 transferred from the 27th April, 1988.

The drugs include Salts, Esters, derivatives etc. However, till the prices of bulk drugs are revised as per the DPCO, 1987, the bulk drug prices announced under DPCO, 1979 will continue.

Companies applying for the fixation of prices of bulk drugs either as a result of changes in the category of drugs or a drug which is price decontrolled under DPCO, 1979 becoming the price controlled under DPCO, 1987 or otherwise, may make applications to the BICP in form No. I under intimation to the Deptt. of Chemicals and Petro-Chemicals.

II. *Formulations*

All formulations covered under Third Schedule are price controlled. In case of drugs appearing under both the First and Second Schedules, the formulations dosage forms (single ingredient or combination), shall be considered as Category I formulations if they are recommended for use in the treatment of the disease under which the drug is included under First Schedule. All other formulations will be considered as Category II formulations.

In case of formulations of Scheduled bulk drugs and non-scheduled bulk drugs, the drug will be considered to be price controlled, if the scheduled bulk drug forms major therapeutic ingredient.

All combinations containing Vitamin(s) will be treated as Category II formulations.

The final authority to decide whether a formulation is a Scheduled formulation or otherwise and its Categorisation rests with the Government. For this purpose, all manufacturers/importers shall submit a list of formulations (licensed to manufacture under Drugs & Cosmetics Act) with proper classification within 45 days from the date of issue in case of existing products and 45 days from the date of grant of permission under Drugs & Cosmetics Act in case of new products.

III. *Application for price revision*

All applications for price fixation/revision and the representations submitted against the prices fixed under DPCO, 1979 stand disposed of. The prices fixed under DPCO, 1979 prevail in case the manufacturers desire to have revised prices for such formulations, they should submit fresh applications under the provisions of DPCO, 1987.

The manufacturers are free to revise the prices of non-scheduled formulations subject to following the procedure provided under Paragraph II. They are required to furnish information on cost details to the Government.

IV. *Mape*

For the purpose of regulating MAPE, the Government will grant 75 per cent for Category I formulations and 100 per cent for Category II formulations.

Price of Tetanus Antitoxin

666. DR. RATNAKAR PANDEY: Will the Minister of INDUSTRY be pleased to refer to the answer to Unstarred Question 3522 given in the Rajya Sabha on 28th March, 1988 and state:

(a) whether it is a fact that Tetanus Antitoxin was under price control under DPCO, 1979;

(b) whether it is also a fact that price was not fixed by his Ministry for seven years;

(c) if so, what were the specific reasons for delay;

(d) whether it is a fact that producers have increased the prices of Tetanus Antitoxin by 200 per cent of the price recommended by BICP;